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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/13/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/462,472

Applicant(s)
Matsui et al.

Examiner
Christian L. Fronda

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1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. In the **AMENDMENT AND REQUEST FOR RECONSIDERATION** (Paper No. 10), Applicants have amended claim 13 and added new claims 14-23.
2. Claims 13-26 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 13-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method for producing a purine nucleoside by fermentation using any microorganism that belongs to the genus *Escherichia* which has an increase in any enzyme involved in purine nucleoside biosynthesis. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific organism and the specific mutations to specific enzymes/proteins involved in purine nucleoside biosynthesis is lacking. Thus, searching for the specific organism and the specific mutations to specific enzymes/proteins involved in purine nucleoside biosynthesis is well outside the realm of routine experimentation and predictability in the art of success in determining any specific enzymes/proteins involved in purine

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nucleoside biosynthesis is extremely low.

The amount of experimentation to determine the specific organism and the specific mutations to specific enzymes/proteins involved in purine nucleoside biosynthesis is enormous and entails screening a vast number of organisms, identifying any and all enzymes involved in purine nucleoside biosynthesis, and determining and performing any mutations to the identified enzyme which would result in increased enzyme activity. Since routine experimentation in the art does not include screening vast numbers of organisms and enzymes/proteins involved in purine nucleoside biosynthesis, where the expectation of obtaining a desired organism and enzyme/protein involved in purine nucleoside biosynthesis is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific enzyme/protein and the specific mutation which would result in an increase of enzyme activity. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 13-16 and 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, the phrase "activity increase of an enzyme involved in purine nucleoside biosynthesis" renders the claim vague and indefinite because the specific enzyme is not known and not recited in the claim.

In claim 14, the phrase "an increase of an expression amount of a gene for an enzyme involved in purine nucleoside biosynthesis" renders the claim vague and indefinite because the specific gene is not known and not recited in the claim.

In claim 15, the phrase "deregulation of control of an enzyme involved in purine nucleoside biosynthesis" renders the claim vague and indefinite because the specific enzyme which is deregulated is not known and not recited in the claim.

In claim 16, the phrase "control of the enzyme involved in the purine nucleoside biosynthesis is desensitized by desensitization of feedback inhibition" renders the claim vague and indefinite because the specific enzyme which is desensitized by desensitization of feedback inhibition is not known and recited in the claim.

In claim 22, the phrase "derepressed by inactivation of a purine repressor" renders the

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claim vague and indefinite because the specific identity/structure of the claimed "purine repressor" is not known and recited in the claim.

In claim 23, the phrase "a reaction branching from purine nucleoside biosynthesis and leading to another metabolite is blocked" renders the claim vague and indefinite because the specific reaction and enzyme involved in the reaction as well as the metabolite is not known and not recited in the specification. Furthermore, claim 23 recites the limitation "a reaction branching from purine nucleoside biosynthesis and leading to another metabolite is blocked". There is insufficient antecedent basis for this limitation in the claim. Claim 24 which depends from claim 23 is also rejected because claim 23 does not correct the defect of claim 24.

In claim 25, the phrase "enhanced by weakening the incorporation of a purine nucleoside" renders the claim vague and indefinite because the specific reaction/enzyme which is involved in the incorporation of a purine nucleoside is not known and not recited in the claim. Furthermore, claim 25 recites the limitation "enhanced by weakening the incorporation of a purine nucleoside". There is insufficient antecedent basis for this limitation in the claim. Claim 26 which depends from claim 25 is also rejected because claim 26 does not correct the defect of claim 25.

In claim 26, the phrase "weakened by blockage of a reaction involved in the incorporation of the purine nucleoside into cells" renders the claim vague and indefinite because the specific reaction/enzyme which is weakened by blockage of a reaction involved in the incorporation of a purine nucleoside is not known and not recited in the claim. Furthermore, claim 26 recites the limitation "weakened by blockage of a reaction involved in the incorporation of the purine nucleoside into cells". There is insufficient antecedent basis for this limitation in the claim.

Conclusion

7. No claim is allowed.

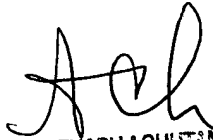
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF


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